SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER k060130

Beckman Coulter Immunoglobulin A Low Concentration (IGALC) Reagent

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
Beckman Coulter Immunoglobulin A Low Concentration (IGALC) Reagent (k993549).

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The modifications were: a) change the IGALC reagent serum method comparison of IgA equivalency values to reflect performance of the current reagent production process and b) change the statistical slope specification from the original slope claim of 0.973 to the new slope claim of 0.865.
4. **Comparison Information** (similarities and differences) to the applicant's legally marketed predicate device include labeling, intended use, sample type, antibody, method principle, instrumentation, sample volume, reference interval values and method comparison.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. The risk analysis method used to assess the impact of the device modification was a Failure Modes and Effects Analysis (FMEA) (page 5 of 1/20/06 response).
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied (page 5 of 1/20/06 response).
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, (page 17 of 1/17/06 original document) and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21

CFR 820.30 and the records are available for review (page 18 of 1/17/06 original document).

6. A **Truthful and Accurate Statement**, a **510(k) Summary,** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.